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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,365	07/30/2001	Eugene T. Michal	ACS 55933	1073

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EXAMINER	
CAMERON, ERMA C	

ART UNIT	PAPER NUMBER
1762	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/918,365	MICHAL ET AL.	
	Examiner	Art Unit	
	Erma Cameron	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *19-33 and 35-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 3, 4, 7, 10-11, 13, 15-17, and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang et al. (6,358,557).

Wang et al. teaches a method for immobilizing anti-thrombogenic agents in a coating on an implantable medical device (col. 1, lines 10-14; col. 11, line 23) by applying a base coat mixture directly to the device (col. 6, lines 10-14), polymerizing the base coat mixture, and immobilizing the anti-thrombogenic agent via functional groups of the polymerized base coat (col. 11, lines 28-35).

The dip-coating method of Wang will inherently coat the outside surface of the medical device.

Wang's base coat mixture contains a grafting material, i.e., the monomers to be polymerized; additional monomers, polymers, and crosslinkers, which would act as the binding

materials of Applicant (col. 8, lines 30-40 and throughout); a photoinitiator (col. 8, line 61); and a solvent (col. 8, line 28 and throughout).

Wang teaches the use of acrylates, vinyls, and urethane as the monomers to be polymerized (col. 10, Examples, and throughout), acting as the grafting material of Applicant. Wang teaches the use of a ketone compound (MEK) as the solvent (col. 12, line 25; Ex. 8). Wang teaches heparin, specifically, benzalkonium heparin or TDMAC, both taught in the instant specification as the types of heparin meeting the claims (col. 11, line 25), as the anti-thrombogenic agent.

End-immobilization occurs via the pendant amine group of the heparin compound.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 2, 8-9, 12, 14, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al.

Wang teaches that which is disclosed above.

Additionally, Wang teaches that the method of his invention is useful for coating medical devices which are inserted into blood vessels (col. 1, line 12). Such devices are inclusive of stents. It would have been obvious to one of ordinary skill in the art to use the method of Wang to coat stents, which are inserted into blood vessels, with the expectation of successful results since Wang teaches the use of his invention on such devices.

Wang teaches the use of a combination of materials to form the base coat layer, including polyurethane and several acrylates. It is Examiner's position that the specific choice of polyurethane acrylate for the coating would have been within the skill of an ordinary artisan given Wang's teachings of polyurethane and acrylates as the coating materials.

While Wang teaches the use of photoinitiators, above, and that the use of UV treatments to graft polymers is well-known in the art (col. 2) he teaches that there are some disadvantages of using UV radiation when tubing is being coated. Thus, he does not exemplify any durations of UV irradiation. However, stents are not solid tubes and therefore, photo-induced grafting does not yield the disadvantages in stents as discussed by Wang in the coating of, for example, catheters. Therefore, it would have been obvious to one of ordinary skill in the art to select UV-

irradiation as a means for grafting/polymerizing the monomers of Wang and to select an appropriate time to carry out such irradiation depending on the types of monomers used, the concentration of photoinitiator used, and the degree of polymerization/grafting desired. It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

While Wang teaches immobilization of heparin to the chemically functional groups within the base coat layer, above, the reference fails to state that the heparin is applied in aqueous solution. However, Examiner notes that heparin is water-soluble and that water is a safe, pH-neutral solvent for use on medical devices that will be placed within the body, therefore, it is Examiner's position that the use of water as a medium for coating the medical device of Wang would have been obvious to one of ordinary skill in the art. The timeframes and temperatures used in this coating step would have been optimized by one of ordinary skill in the art for those reasons outlined above.

6. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang in view of Fan et al. (5,620,738).

Wang teaches that which is disclosed above regarding polymerizing acrylate, etc. monomers directly onto a medical device and immobilizing heparin thereon. While Wang teaches compounds that would act as a binder in such a process, Wang fails to teach the specific binders of Applicant.

Fan teaches that it is known to attach lubricious acrylic-based polymers to stents using a binder polymer with aldehyde or isocyanate functional groups (col. 1, throughout).
Since Wang teaches grafting coatings onto medical devices and Fan teaches the use of the specific binder polymers of Applicant to do so, it would have been obvious to an ordinary artisan to use the aldehyde or isocyanate binders of Fan in the method of Wang with the expectation of successful results since Fan teaches that such binders are well-known in such coating applications. Aldehydes are inclusive of cinnamaldehyde.

Response to Arguments

7. Applicant's arguments filed 9/13/2006 have been fully considered but they are not persuasive.

The applicant has attempted to swear behind 6221425 in the 1.131 Declaration of 9/13/2006. However, this does not give a prior-to-9/10/1999 date to 09/918365, as 6221425 and 09/918365 are not related. (In addition, there is no Appendix A that is referred to.)

NEW REJECTIONS

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO99/38546.

'546 teaches applying to a stent or other device a composition comprising a binding component of isocyanate, a grafting component of acrylate groups (such as urethane acrylate), a photoinitiator and a ketone solvent and polymerizing the composition with UV light. The composition may contain heparin and cinnamaldehyde (see Claims and page 4-19). The heparin binds to the binding component, thus immobilizing it (see claim 1).

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-18 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is not clear from independent claims 1 and 34 how the anti-thrombogenic material is immobilized within the base coat layer when there is no statement that the anti-thrombogenic material is actually added to the base coat layer or when.

12. Claims 1-18 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is not clear how the polyurethane of the title is created when most of the materials of the base coat layer do not have to contain any urethane or isocyanate groups (see claim 5 for instance).

13. Claims 1-18 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At 5:1-2 and 7:23-25 it is stated that the anti-thrombogenic material is attached through at least one intermediate component, but it is not clear from the claims what that intermediate component is.

14. Claims 1-18 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

17:16 and perhaps elsewhere: the term "peglated" is unclear.

15. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The examiner cannot find where in the specification the parameters of claim 14 are described.

16. Claims 1-8, 10-18 and 34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polymerizing the base coat mixture with UV light, does not reasonably provide enablement for any means of polymerization. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It appears that UV is the only method of polymerizing the base coat mixture, according to the specification.

17. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

18. Claims 1-18 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claims 1 and 34: it is not clear if the "coating" of line 2 of each claim is the same or different from the base coat layer of later lines.

b) There is no antecedent basis for

claim 5 the base coat

claim 7 the base coat

c) Claim 34: it is not clear how a coating (line 2) is formed, because the application of the base coat mixture to the device is not cited.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Erma Cameron whose telephone number is 571-272-1416. The examiner can normally be reached on 8:30-6:00, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Erma Cameron

ERMA CAMERON
PRIMARY EXAMINER

Erma Cameron
Primary Examiner
Art Unit 1762

December 11, 2006